

### **DETAILED ACTION**

Applicant's arguments and declaration filed April 6, 2010 have been received and entered. Applicants have amended claims 1-2, 9, 11, 13, 15, 20-21, 24, 39, 41, 44 and 45, while claims 4-8, 22-2333-34 and 43 have been canceled. Claims 1-3, 9-15, 20-21, 24, 30-32, 35-42, 44 and 45 are pending in this application.

#### ***Election/Restrictions***

Applicant's election of claims 1-16, 20-21, 29-32 and 35-41 in the reply filed on January 19, 2006 was acknowledged. The applicants elected muscle specific promoter for examination. Claims 1-3, 9-15, 20-21, 24, 30-32, 35-42, 44 and 45 are currently under examination.

#### ***Oath/Declaration***

The Gong declaration filed on May 4, 2010, is sufficient to remove the availability of Hua et al (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS, filed 9/17/09) and Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS) references applied under different 35 U.S.C. 103(a).

#### ***Withdrawn-Claim Rejections - 35 USC § 103***

Claims 1, 36-37, 39-40, 42-45 were rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et al (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS, filed 9/17/09) and Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883). Applicants' submission of The Gong's declaration removes the availability of Higashijima et al and Hua et al reference from all obviousness type rejection. It is noted that Gong et al provide the declaration based on his personal knowledge of the departmental practice that reference of Hua et al was never maintained, indexed or catalogued in National Library of Singapore. Additionally, The Gong declaration further states that one of the co author of Higashijima et al paper specifically stated to him that no visible fluorescent color could be seen under normal

daylight in the adult green fluorescent protein- expressing fish described in the referenced Higashijima *et al.* article. In view of foregoing and testimony of Gong *et al*, the rejection is hereby withdrawn.

Claims 2-3 were rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima *et al* (Dev Biol. 1997; 192(2): 289-99, IDS), Hua *et al* (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong *et al* (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Abeywickrama *et al* (US Patent no: 5028839, dated 7/2/1991). The rejection is withdrawn for the reasons discussed above.

Claim 21 was rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima *et al* (Dev Biol. 1997; 192(2): 289-99, IDS), Hua *et al* (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong *et al* (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Moss *et al* (Gene. 1996; 173: 89-98, IDS). The rejection is withdrawn for the reasons discussed above.

Claim 20 was rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima *et al* (Dev Biol. 1997; 192(2): 289-99, IDS), Hua *et al* (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong *et al* (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Liao *et al* (Analytical Biochemistry, 253, 1997, 137-139, IDS). The rejection is withdrawn for the reasons discussed above.

Claim 38 was rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima *et al* (Dev Biol. 1997; 192(2): 289-99, IDS), Hua *et al* (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong *et al* (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36-37, 39-40, 42-45 above,

and further in view of Culp et al (PNAS, 1991, 88, 7953-7957) . The rejection is withdrawn for the reasons discussed above.

Claim 41 was rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et al (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36, 43 above, and further in view of Lin et al (US patent application no 20020178461, dated 4/30/2002 effective filing date 6/9/1997) or Hernández et al (Mol Mar Biol Biotechnol. 1997 Dec;6(4):364-75). The rejection is withdrawn for the reasons discussed above.

Claims 9-11, 15, 24, 30-32, 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et al (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Flanagan (Virus Genes, 1987, 1:61-71) and Chalfie, et al Green fluorescent protein: properties, applications, and protocols, Wiley-Liss, New York, 1998, art of record). The rejection is withdrawn for the reasons discussed above.

Claims 11-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et al (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Yang et al (1998; 273(14):8212-6, IDS) and Living Colors Subcellular Localization Vectors (October 1998) CLONTECHniques XIII (4):8-9, art of record). The rejection is withdrawn for the reasons discussed above.

Claims 1, 36-37, 39-40, 42-44 and 45 were rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS) and Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235). The rejection is withdrawn for the reasons discussed above.

***Withdrawn-Double Patenting***

Claims 1-3, 9-15, 20-21, 24, 30-32, 35-44 and 45 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-46, 53-55, 58-60, 63-65, 68-81 of copending Application No. 11/749032. The rejection of claims is hereby withdrawn because 11/749032 has not been allowed.

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Parker on May 20, 2010.

The application has been amended as follows:

***In the Specification***

Replace continuation data on the first page of the specification as follows:

--This application is a DIV of application no. 09/913,898, filed October 3, 2001, now U.S. patent 7,135,613, which is a national stage of PCT application WO 00/49150 filed July 16, 1999, claiming priority over a Singapore application filed July 14, 1999, and an earlier Singapore application, Serial No. 9900811-2, filed February 18, 1999. -- .

***In the claims***

Claims 24 and 35 have been canceled.

In claim 9, the term "BFP" in line 2 has been replaced with --blue fluorescent protein (BFP)--.

In claim 10, the term “EBFP” in line 1 has been replaced with -- enhanced blue fluorescent protein (EBFP)--.

In claim 11, the term “YFP” in line 2 has been replaced with --yellow fluorescent protein (YFP)--.

In claim 12, the term “EYFP” in line 1 has been replaced with -- enhanced yellow fluorescent protein (EYFP)--.

In claim 13, the term “CFP” in line 2 has been replaced with --cyan fluorescent protein (CFP)--.

In claim 14, the term “ECFP” in line 1 has been replaced with -- enhanced cyan fluorescent protein (ECFP)--.

In claim 44, the term “GFP” in line 2 has been replaced with -- green fluorescent protein (GFP)--.

In claim 45, the term “EGFP” in line 2 has been replaced with -- enhanced green fluorescent protein (EGFP)--.

Following claims have been re-written as follows.

1. A method of providing transgenic fish to the ornamental fish market, comprising the steps of: (a) obtaining a transgenic fish line comprising one or more fluorescence genes that are positioned under the control of a muscle specific promoter, such that said transgenic fish expresses fluorescent protein encoded by said fluorescence gene(s) in skeletal muscle such that said transgenic fish visually exhibits expression of fluorescent protein(s) upon exposure to sunlight, wherein said transgenic fish are the offspring of an embryo line visually exhibiting expression of fluorescent protein(s) in essentially all muscle fibers in their trunk and further wherein transgenic founders of said fish line visually exhibits expression of fluorescent protein(s) upon exposure to

sunlight; and

(b) distributing fish of said line to the ornamental fish market.

30. The method of claim 15, wherein more than one fluorescent protein is expressed in the same muscle tissue, to produce a fluorescent color.

32. The method of claim 15, wherein more than one fluorescent protein are separately expressed in different muscle tissues.

36. The method of claim 1, wherein the transgenic fish is a stable transgenic fish line obtained by a method comprising the steps of:

- (a) obtaining a transgenic fish comprising one or more fluorescence genes positioned under the control of a muscle specific promoter, wherein the transgenic fish expresses one or more fluorescent proteins encoded by the one or more fluorescence genes; and
- (b) breeding the transgenic fish with a second fish of the same species to obtain offspring; and
- (c) selecting from said offspring a stable transgenic line that expresses one or more fluorescent proteins in its muscle tissue.

**Claims 1-3, 9-15, 20-21, 30-32, 36-42, 44 and 45 are allowed.**

**Examiner's comment:**

The title of the instant application has been changed to – Sale of Transgenic Fish that Express Gene Encoding Fluorescent Protein –.

***Conclusion***

The following is an examiner's statement of reasons for allowance: At the time of filing transgenic fish expressing a fluorescent protein where made and used, however transgenic fish that expresses fluorescent protein in skeletal muscle at a level sufficient such that said transgenic fish fluoresces upon exposure to sunlight was not known. The instant specification is the first to

envision and produce a transgenic fish line from an embryo line visually exhibiting expression of the fluorescent protein in essentially all the muscle fibers and in their trunk upon exposure to sunlight and is the first to disclose the use of said fluorescent transgenic fish for distribution to the ornamental fish market for display purposes.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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